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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------|------------------|
| 10/696,969  | 10/30/2003  | Jason A. Demers      | 1062/D70             | 8503             |
| 2101  | 7590        | 03/07/2006           | EXAMINER             |                  |
| BROMBERG & SUNSTEIN LLP<br>125 SUMMER STREET<br>BOSTON, MA 02110-1618 |             |                      | BRADRIK, THOMAS DALE |                  |
|   |             |                      | ART UNIT             | PAPER NUMBER     |
|   |             |                      | 1651                 |                  |
| DATE MAILED: 03/07/2006   |             |                      |                      |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/696,969

Applicant(s)

DEMERS ET AL.

Examiner

Thomas D. Bradrick

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 1-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/29/04, 7/1/05 & 12/15/05
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-65 are pending. Claims 26-65 are being examined on the merits.

Claims 1-25 are withdrawn from examination as being drawn to a non-elected invention.

Election was made **without** traverse in the reply filed on September 19, 2005.

Applicant's request that the restriction requirement filed on August 6, 2005 be reconsidered and modified is acknowledged. Upon reconsideration of the restriction requirement, claims 49-65 are hereby rejoined with claims 26-48 and are together examined on the merits.

### ***Specification***

The attempt to incorporate subject matter into this application by reference to United States Patent Application Numbers "XX/XXX,XXX" (p. 1) is ineffective because the assigned application numbers are not thereby actually included.

The use of the trademarks PEN110 and INACTINE (p. 8, l. 15) has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 recites that the container assembly and liquid controllers are to be “operatively coupled” with the receiving chamber. It is unclear what this means. Is said coupling to take place as part of a mechanical operation (e.g., movement on the part of either controller or the receiving chamber), or are they to be coupled or linked together in terms of how they operate (e.g., functionally)? Applicant has not made this clear. Further, it is unclear what the “receiving chamber” comprises in that the specification does not discuss this structure in reference to the drawings. Also, there is no antecedent basis or description of the following elements in the specification disclosure: “container assembly controller” (claim 26, line 7); “liquid controller” (claim 26, line 10); “cover lock” (claim 32); and “pneumatically controlled member” (claim 33).

Claim 36 recites the limitation “wherein the receiving chamber at least partially extends outwardly from the housing” in claim 26. There is insufficient antecedent basis for this limitation in the claim. No such “housing” is specified in claim 26.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26-29, 34-42, 49-52 and 57-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Bloom *et al.* (USP 6,070,761), cited by Applicants.

Claim 26 is drawn to an apparatus for mixing a substance with a liquid, the substance being contained in a container assembly having i) a sealed container that contains the substance and ii) a port assembly that permits the substance to flow from the sealed container when coupled, the apparatus comprising a) a receiving chamber for receiving the container assembly; b) a container assembly controller operatively coupled with the receiving chamber and controlling coupling of the container and port assembly; and c) a liquid controller operatively coupled with the receiving chamber and controlling the flow of liquid into the container. Claim 27 specifies that the liquid controller control both the flow of liquid into the container and flow of the mixture out of the chamber (d), while claim 28 specifies that the container assembly controller mechanically move at least a portion of the container assembly to couple the container with the port assembly (e). Claim 29 specifies that the container assembly controller include logic for detecting the relative locations of the container and port assembly (f). Claims 34-42 further specify that the liquid controller include logic that stores a value representing a predetermined amount of liquid to be received by the container

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assembly; that the apparatus further comprise a housing containing at least one of the container assembly controller and the liquid controller; that the receiving chamber at least partially extend outward from the housing; that the apparatus further comprise a sensor within the receiving chamber for detecting the location of the container within the receiving chamber; that the receiving chamber be configured to contain the container assembly in a single orientation; that the apparatus further comprise a set of valves controlled by the liquid container to control the flow of liquid into the container; that the apparatus further comprise a cassette used by the liquid controller to measure the volume of liquid to be directed to the container; that the substance is a caustic solution; and that the substance is an anti-pathogen compound, respectively. Claim 49 is drawn to an apparatus for mixing a substance with a liquid, said apparatus comprising means for receiving a container assembly having a sealed container that contains the substance; coupling means for controlling coupling of the container assembly and a port assembly that permits the substance to flow from the sealed container when coupled; and a flow means for controlling the flow of the liquid into the container to produce a combined substance and liquid. Claim 50 further specifies that the flow means also control the flow of the combined substance and liquid from the container; claim 51 further specifies that the coupling means include means for mechanically moving at least a portion of the container assembly to couple the container with the port assembly; and claim 52 further specifies that the coupling means include means for detecting the relative locations of the container and the port assembly. Claim 57-65 further specify that the flow means include means for storing a value representing a predetermined

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amount of liquid to be received by the container assembly; that the apparatus further comprise a housing containing at least one of the coupling means and the flow means; that the receiving means at least partially extend outwardly from the housing; that the apparatus further comprise a means for detecting the location of the container within the receiving means; that the receiving means be configured to contain the container assembly in a single orientation; that the apparatus further comprise a set of valves controlled by the flow means to control flow of liquid into the container; that the apparatus further comprise a means for measuring the volume of the liquid to be directed to the container, the measuring means being used by the flow means; and that the substance be either caustic or anti-pathogenic, respectively.

Bloom *et al.* teach an apparatus (Figure 13) for mixing a substance with a liquid comprising: a sealed container 85; port assembly 118; receiving chamber 202 with hinged cover 86 for receiving the container; controller 207 for controlling coupling of the container and the port assembly (col. 17, ll. 8-26); and liquid controller 88 comprising a cassette 77 and valves 112 (col. 16, ll. 54-64). The liquid controller controls flow of liquid to and from the container (col. 15, ll. 47-58 and col. 16, ll. 54-64). With regard to instant claims 37 and 60, Bloom *et al.* also teach a container sensing device at col. 19, ll. 53-54.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 26, 33, 49 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom et al. as applied to claims 26-29, 34-42, 49-52 and 57-65 above in view of Ko (U.S. Patent 6,527,758).

Claim 33 is drawn to the apparatus of claim 26 as further including a pneumatically controlled member within the receiving chamber, the pneumatically controlled member being capable of contributing to the coupling of the container assembly in response to commands from the container assembly. Claim 56 is drawn to the apparatus of claim 49 as further including a pneumatically controlled means within the receiving means, the pneumatically controlled means being capable of contributing to the coupling of the container assembly in response to commands from the coupling means.

With regard to claims 33 and 56, Bloom *et al.* do not teach a pneumatically controlled member for contributing to the coupling of the container assembly. In Bloom *et al.*, the container holder 207 is manually lowered by the clinician so that the spike 118



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pierces the seal of the container 85. Ko teaches means for moving the spouts of containers into coupling engagement with receptacles at a docking station wherein the moving means comprises either manually controlled driven cams (22, 23; figures 2-5) or pneumatically controlled means 29 (figure 10; col. 5, ll. 55-62). It therefore would have been obvious to one of ordinary skill in the art at the time the invention was made to use pneumatic means for contributing to the coupling of the container assembly of Bloom *et al.* in view of the teaching of Ko that pneumatic means can be used in place of manual means for moving containers into coupling engagement with receptacles at a docking station.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Bradrick whose telephone number is 571-272-8139. The examiner can normally be reached Monday through Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1651



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